UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

LEON D. BOROCHOFF, On Behalf of Himself and All Others Similarly Situated, Civil Action No. 1:07-cv-05574-LLS

(Consolidated)

Plaintiff, **CLASS ACTION**

[PROPOSED] SECOND AMENDED VS. COMPLAINT FOR VIOLATION OF THE

FEDERAL SECURITIES LAWS

GLAXOSMITHKLINE PLC, et al.,

Defendants.

Lead Plaintiff Avon Pension Fund, Administered by Bath & North East Somerset Council ("Avon Pension Fund") and Plaintiffs Plumbers & Steamfitters Local 773 Pension Fund ("Plumbers & Steamfitters Local 773") and Plumbers' Union Local No. 12 Pension Fund ("Plumbers' Union Local No. 12") (collectively, "Plaintiffs"), individually and on behalf of all other persons similarly situated, allege the following based upon personal knowledge as to them and their own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through their attorneys, which included, among other things, a review of the public documents and announcements concerning GlaxoSmithKline PLC ("Glaxo," "GSK" or the "Company"), United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Glaxo, information readily available on the Internet and review of "The Intimidation of Dr. John Buse and the Diabetes Drug Avandia," Committee Staff Report to the Chairman and Ranking Member United States Committee on Finance, November 2007. Plaintiffs believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

- 1. This is a federal securities class action brought against Glaxo and certain of its directors and officers on behalf of purchasers of Glaxo American Depository Shares ("ADSs") and ordinary shares between October 27, 2005 and May 21, 2007 (the "Class Period"), for violations of the Securities Exchange Act of 1934 (the "Exchange Act").
- 2. Defendant Glaxo develops, produces and sells pharmaceuticals, over-the-counter (OTC) medicines, vaccines and health-related consumer products. Glaxo's products are sold in over 125 nations and it has primary operations in 116 countries. This case concerns materially false statements and omissions concerning one of Glaxo's key drug products, Avandia, which is used in the treatment of Type 2 diabetes.

- 3. In 1999, Glaxo received approval to market Avandia (rosiglitazone maleate). Since that time, the Company has sought to obscure and conceal the fact that the use of Avandia leads to an increased risk of heart attack. Glaxo concealed the truth about Avandia from the public and investors for as long as possible because disclosure of an increased risk of heart attack from use of Avandia would lead to a dramatic decline in sales of the drug.
- 4. At the time that Avandia was approved by the United States Food and Drug Administration (the "FDA"), Dr. John Buse ("Buse"), a well-known independent scientist, raised concerns that the use of Avandia could lead to adverse cardiovascular events. Glaxo responded by complaining to Buse's superiors at the University of North Carolina and threatening litigation. Eventually, Glaxo was successful in intimidating Buse and stopping him from publicly raising concerns about Avandia and adverse cardiovascular events. Instead of taking the necessary steps to investigate the concerns raised by Buse, Glaxo acted to protect its Avandia franchise by concealing, for as long as possible, the connection between Avandia and adverse cardiovascular events. Glaxo's actions towards Buse evidence that the Company viewed any public statement linking use of Avandia to adverse cardiovascular events, particularly a significant link, to be highly detrimental for sales of the drug.
- 5. Then, in 2005, Glaxo completed two analyses of data based on 42 clinical trials of Avandia (the "Meta-Analyses"). The Meta-Analyses concluded that the use of Avandia presented an increased risk of heart attack and that this increased risk was statistically significant. Yet, Glaxo did not disclose its conclusions to the public or investors. Instead, throughout the Class Period, Defendants issued positive statements about Avandia, its contribution to the Company's financial results and positive results from Avandia-clinical trials without disclosing what they knew -- that use

of Avandia was associated with an increased risk of heart attack and the Company had completed analyses that reached that conclusion.

- 6. Ultimately, Glaxo was unable to continue to conceal the truth about Avandia and heart attacks. On May 21, 2007, *The New England Journal of Medicine* published a meta-analysis conducted by Dr. Stephen Nissen entitled "Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes," which concluded that Avandia poses a statistically significant risk of cardiac side-effects. Specifically, the article stated that "[R]osiglitazone [Avandia] was associated with a [statistically] significant increase in the risk of myocardial infarction." Later that same day, the FDA issued a safety alert, which recognized an increased risk of heart attack from the use of Avandia. In response to these announcements, by May 29, 2007, the prices of Glaxo securities declined dramatically Glaxo ADSs declined from \$57.71 per ADS to \$52.06 per ADS and Glaxo ordinary shares declined from 1464 pence per share to 1306 pence per share.
- 7. Shortly after these announcements, in May 2007, the United States Senate Committee on Finance (the "Finance Committee") held hearings to investigate accusations that Glaxo had intimidated or attempted to silence medical professionals who had raised concerns about the potential for cardiovascular problems with Avandia. In November 2007, the Finance Committee issued a report entitled "The Intimidation of Dr. John Buse and the Diabetes Drug Avandia." In the report, the Finance Committee described the findings of its investigation in detail. The Finance Committee found that, in 1999, Buse had expressed concerns regarding the cardiovascular risks including heart attacks associated with Avandia. Glaxo was not only knowledgeable about the link between Avandia and heart attacks, but, according to the Finance Committee's report, Defendants Jean-Pierre "JP" Garnier ("Garnier") and David Stout ("Stout"), as well as then research chief for the

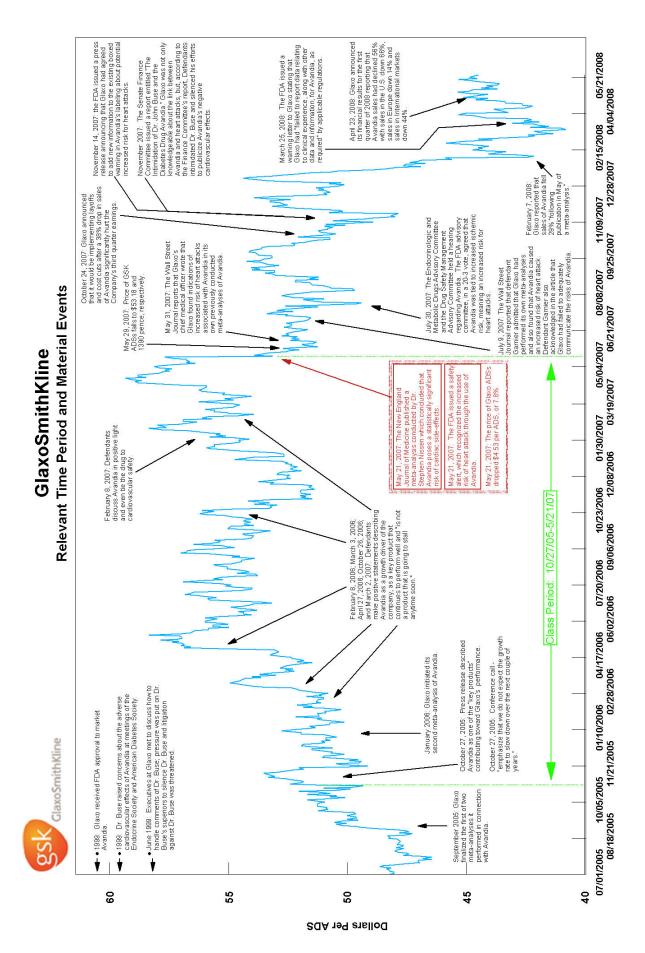
Company, Tachi Yamada, were participants in a concerted effort to intimidate Buse and silence his efforts to publicize Avandia's potential negative cardiovascular effects. The Finance Committee's report stated that Glaxo stifled Buse by complaining to his superiors at the University of North Carolina, calling him a "renegade" and ultimately threatening him with the prospect of facing a lawsuit.

- 8. The FDA also convened committee meetings to review Avandia and the risk of heart attacks. As detailed further herein, the FDA committee concluded that the use of Avandia was associated with a statistically significant increased risk of heart attack.
- 9. On November 14, 2007, the FDA issued a press release announcing that Glaxo had agreed to add new information to the existing boxed warning in Avandia's labeling about potential increased risk for heart attacks.
- Subsequently, the FDA also cited Glaxo for failing to properly report Avandia-related study information to the FDA and noted that Glaxo's reporting practices were not conducive to the FDA's monitoring of safety trends. On March 25, 2008, the FDA issued a warning letter to Glaxo (the "FDA Warning Letter") which stated, among other things, that Glaxo had "failed to report data relating to clinical experience, along with other data and information, for Avandia, as required" by applicable regulations. In addition, the FDA Warning Letter indicated that Glaxo had failed to report nine Avandia-related studies to the FDA and that those studies were not disclosed to the FDA until Glaxo made an amendment to its 2007 NDA Annual Report in September 2007.
- 11. The public revelations concerning Dr. Nissen's meta-analysis and the FDA's safety alert dramatically impacted sales of Avandia. On October 24, 2007, Glaxo announced that it would be implementing layoffs and cost cuts after a 38% drop in sales of Avandia significantly hurt the Company's third quarter earnings. On February 7, 2008, Glaxo reported a 12% drop in fourth quarter

profit and warned that earnings for 2008 would drop as well, hurt by declining sales of Avandia. Sales of Avandia for the fourth quarter dropped 29% in the U.S., amid concerns that the drug posed cardiovascular risks. On April 23, 2008, Glaxo announced its financial results for the first quarter of 2008 and reported that Avandia sales had declined 56%, with sales in the U.S. down 66%, sales in Europe down 14% and sales in international markets down 44%. In short, Avandia sales have plummeted after it was revealed that a meta-analysis evidenced a connection between Avandia and an increased risk of heart attack.

12. The following chart graphically depicts Defendants' fraudulent scheme, key events during the Class Period and the devastating impact of the fraud on Lead Plaintiff and the Class:

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JURISDICTION AND VENUE

- 13. Jurisdiction is conferred by Section 27 of the Exchange Act. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the SEC [17 C.F.R. §240.10b-5].
- 14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, and Section 27 of the Exchange Act [15 U.S.C. §78aa].
- 15. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. §1391(b). Many of the acts and practices complained of herein occurred in substantial part in this District. Also, Glaxo's ADSs, which each represent two ordinary shares of Glaxo ordinary stock, are, pursuant to agreement with the Bank of New York, listed on the New York Stock Exchange ("NYSE"), which is located in this District.
- 16. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

- 17. Lead Plaintiff Avon Pension Fund purchased Glaxo ordinary shares during the Class Period, as detailed in the certification previously filed in this case and incorporated herein by reference, and was damaged thereby.
- 18. Plaintiff Plumbers & Steamfitters Local 773 purchased Glaxo ADSs during the Class Period, as detailed in the certification previously filed in this case and incorporated herein by reference, and was damaged thereby.
- 19. Plaintiff Plumbers' Union Local No. 12 purchased Glaxo ordinary shares during the Class Period, as detailed in the certification previously filed in this case and incorporated herein by reference, and was damaged thereby.

- 20. Defendant Glaxo develops, produces and sells pharmaceuticals, OTC medicines, vaccines and health-related consumer products. Glaxo's products are sold in over 125 nations and it has primary operations in 116 countries. The Company's operations are principally based in two industry segments: consumer healthcare (nutritional healthcare, OTC medicines and oral care) and pharmaceuticals (vaccines and prescription pharmaceuticals). In 2000, Glaxo Wellcome and SmithKline Beecham merged to form Glaxo. That same year, shares of the new company began trading on the London Stock Exchange ("LSE") and the NYSE. Glaxo also has extensive operations throughout the United States.
- 21. Defendant Garnier was, at all relevant times, Chief Executive Officer ("CEO") of Glaxo.
- 22. Defendant Stout was, at all relevant times, Glaxo's President, Pharmaceutical Operations.
- 23. Defendant Julian Heslop ("Heslop") was, at all relevant times, Glaxo's Chief Financial Officer ("CFO").
- 24. Defendant Simon Bicknell ("Bicknell") was, at all relevant times, the Company's Secretary.¹

CLASS ACTION ALLEGATIONS

25. This is a class action on behalf of all persons who purchased or otherwise acquired Glaxo ADSs on the NYSE or ordinary shares on the LSE during the Class Period. Excluded from the Class are Defendants; officers and directors of the Company; the immediate families of such

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Defendants Garnier, Stout, Heslop and Bicknell are collectively referred to herein as the "Individual Defendants."

Defendants, officers, and directors; any entity in which any Defendant has or had a controlling interest; and the legal representatives, heirs, successors or assigns of any such excluded person.

- 26. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Glaxo's ADSs and ordinary shares were actively traded on the NYSE and LSE, respectively. As of November 2, 2007, the Company had 2.8 billion shares of its ADSs traded on the NYSE and 5.5 billion ordinary shares traded on the LSE. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Glaxo or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.
- 27. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 28. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are: (a) whether the federal securities laws were violated by Defendants' acts, as alleged herein; (b) whether statements made by Defendants to the investing public during the Class Period were materially false and/or misleading and omitted and/or misrepresented material facts; and (c) to what extent the members of the Class have sustained damages and the proper measure of damages.
- 29. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class action and securities litigation.

30. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

SUBSTANTIVE ALLEGATIONS

The Company and Avandia

- 31. Defendant Glaxo develops, produces and sells pharmaceuticals, OTC medicines, vaccines and health-related consumer products.
- 32. The Company markets Avandia (rosiglitazone maleate) as a drug intended to help improve blood sugar control in type 2 diabetics.
- 33. In 1999, Avandia was approved by the FDA for the treatment of type 2 diabetes. Type 2 diabetes is a life threatening disease that, according to the FDA as of June 2007, affects approximately 18 to 20 million Americans. Since its introduction, the labeling of Avandia has been altered several times, including the addition of a warning for the risk of congestive heart failure. Today, the label for Avandia is required to include a "black box" warning for the risk of heart failure.
- 34. Avandia was Glaxo's second best-selling drug in 2006, with global sales of \$3.38 billion. From 1999 through 2006, Glaxo sold more than \$12 billion worth of Avandia.

A "black box" warning is the most severe or highest level warning that can appear on a drug label, as required by the FDA.

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Glaxo Engages in a Conscious Effort to Suppress Questions About the Use of Avandia and Adverse Cardiovascular Events

- 35. In 1999, Glaxo engaged in a concerted effort to silence Buse, a scientist that was raising concerns about Avandia and its adverse cardiovascular effects.
- 36. In early 1999, Buse gave speeches at meetings of the Endocrine Society and the American Diabetes Society (ADA) in which he was critical of Avandia and its possible adverse cardiac effects.
- 37. In June 1999, executives at Glaxo were discussing Buse and what to do about his negative comments regarding Avandia. Glaxo executives determined to contact Buse's superiors and threaten litigation, among other things. Dr. Tachi Yamada ("Yamada"), Glaxo's head of research, discussed Buse with Defendant Garnier and another Glaxo executive and advised them that he planned to speak to Fred Sparling, who was Buse's superior.
- 38. Yamada called Sparling and, several days later, Buse sent a letter to Yamada explaining his position on Avandia and asking him to "call off the dogs." Buse also included another letter with his explanatory letter. In that letter, Buse attempted to clarify the remarks he had made at medical conferences concerning Avandia. Glaxo executives referred to the second letter as the "Buse retraction letter." These were internal or private communications that were not available to the public or to shareholders.
- 39. On July 1, 1999, Yamada wrote to Buse and thanked him for his explanation. That same day, Glaxo executives and employees discussed Buse in an email chain, with one of them noting that "John Buse kindly signed the clarification letter on his letterhead without any change."
- 40. Following these exchanges, Buse remained publicly silent about his concerns about Avandia, even though he continued to privately voice his concerns. In March 2000, Buse sent a letter to the FDA Commissioner about Avandia and adverse cardiac outcomes. In April 2000, Glaxo

obtained a copy of the letter and sent Buse a letter accusing him of providing the FDA with "several unfair, unbalanced and unsubstantiated allegations."

- Buse remained completely silent on Avandia until October 2005, when he wrote a private email to Dr. Steven Nissen, chairman of the Cardiology Department at the Cleveland Clinic, regarding his concerns about Avandia and its adverse cardiovascular effects. In the email, Buse recounts how he had raised concerns about Avandia and then, after Glaxo called his superiors, he had to sign "some legal document in which I agreed not to discuss this issue further in public. . . . I was certainly intimidated by them but frankly did not have the granularity of data that you had and decided it was not worth it. . . . Again congratulations on that very important piece of work. It makes me embarrassed to have caved in several years ago."
- 42. Glaxo's actions towards Buse evidence that the Company viewed any public statement linking use of Avandia to adverse cardiovascular events as highly detrimental for sales of the drug.

Glaxo Fails to Disclose Internal Studies that Indicate that the Use of Avandia Causes Increased Risk of Heart Attack

43. In September 2005, Glaxo finalized the first of two meta-analyses³ it performed in connection with Avandia. Specifically, Glaxo performed a patient-level meta-analysis of safety data from 37 clinical trials (the "First Meta-Analysis"). Glaxo's First Meta-Analysis showed an estimate of excess risk of ischemic cardiovascular events, *i.e.*, an increased risk of heart attack, associated

to adequately examine a particular question.

A meta-analysis is known as the synthesis of research results through the use of an array of statistical methods to cull and merge results from previously performed separate, but related, studies. This type of analysis is done when the individual studies, alone, would not be deemed large enough

with the use of Avandia. Glaxo did not, however, report or disclose to investors that the results of its First Meta-Analysis showed an increased risk of heart attacks associated with the use of Avandia.

- In January 2006, Glaxo initiated a second meta-analysis of Avandia (the "Second 44. Meta-Analysis"). The Second Meta-Analysis was performed in order to incorporate five additional studies that had been completed between September 2004 and August 2005, for an updated total of 42 clinical trials. The results of Glaxo's Second Meta-Analysis were finalized in March 2006. Glaxo's Second Meta-Analysis showed an estimate of excess risk of ischemic cardiovascular events associated with the use of Avandia that was even greater than the risk portrayed in the First Meta-Analysis. The increased risk of ischemic cardiovascular events presented by the Second Meta-Analysis was statistically significant. Glaxo did not, however, report or disclose to investors that the results of its Second Meta-Analysis showed a risk of heart attacks associated with the use of Avandia that was statistically significant.
- According to the FDA, in August 2006, Glaxo provided the FDA with a pooled 45. analysis (meta-analysis) of 42 separate, double-blinded, randomized, controlled clinical trials to assess the efficacy of Avandia for treatment of type 2 diabetes, compared to either placebo or other anti-diabetic therapies in patients with type 2 diabetes. According to the FDA, it did not publicly discuss the data submitted by Glaxo at the time it was submitted in August 2006 because the FDA wanted to wait until it was able to perform a comprehensive internal re-analysis of that data. The FDA's decision to postpone the release of the potential risks associated with Avandia has caused the FDA to be the target of much criticism and has contributed toward the holding of Congressional hearings to address the FDA's ability to timely respond and alert the public of dangers and risks of drugs as the information becomes available.

- 46. Despite knowing that the data of the Company's meta-analyses showed an increased risk of heart attacks associated with the use of Avandia that was statistically significant, Defendants did not disclose this material information to investors during the Class Period. Instead, Defendants repeatedly highlighted the success of Avandia's sales and the sizeable contribution those sales made to the overall performance and growth of Glaxo without disclosing the material adverse facts they were aware of.
- 47. Moreover, at the same time Defendants were aware of the conclusions from their own meta-analyses, they repeatedly positively highlighted studies which, according to Defendants, demonstrated that Avandia showed (or will show) no increase in myocardial infarctions or cardiovascular-related deaths. For example:
 - A study funded by Glaxo entitled "The Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication" ("DREAM") was published by the Company in September 2006. In summary, Glaxo reported that its review of the cardiovascular data in the DREAM study showed no increased risk for myocardial infarctions or cardiovascular-related deaths from the use of Avandia.
 - A study conducted by Glaxo entitled "A Diabetes Outcomes Progression Trial" ("ADOPT") was published by the Company in December 2006. In summary, Glaxo reported that its review of the data in the ADOPT study showed no statistically significant differences in cardiovascular-related deaths or myocardial infarctions.
 - The "Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes" ("RECORD") study is an ongoing study being conducted by Glaxo. RECORD is a long-term clinical trial that purports to study type 2 diabetes patients, with a focus on determining the cardiovascular-related deaths or hospitalizations resulting from the use of Avandia. The study is reported to be completed in late 2008, with the corresponding results to be published or released in early 2009.

Materially False and Misleading Statements Issued During the Class Period

48. The Class Period starts on October 27, 2005. On that date, Glaxo issued a press release announcing its financial results for its third quarter of 2005, the period ending September 30, 2005. The press release was also filed with the SEC as an exhibit to a Form 6-K, which was signed

by Defendant Bicknell. For the quarter, the Company reported earnings of 21.3p per share, up from 17.7p per share for its third quarter of 2004. With respect to Avandia, the press release described it as one of the "key products" contributing toward Glaxo's "excellent pharmaceutical sales growth." The press release further added:

Commenting on the performance for the quarter and GSK's outlook, JP Garnier, Chief Executive Officer, said: "This quarter's performance shows the vitality of our business, which is again being driven by great performances from key products such as . . . Avandia . . ."

- 49. The statements referenced above in ¶48 were materially false and misleading because they failed to disclose that the Company had completed the First Meta-Analysis, which showed a significant risk of heart attack linked to the use of Avandia. The positive statements made about Avandia and its contributions to the Company's financial results created an obligation to disclose the then-known adverse facts concerning the risks and safety issues attendant to the use of Avandia.
- 50. Also on October 27, 2005, the Company hosted a conference call with analysts and investors to discuss Glaxo's third quarter of 2005 financial results. During the call, Defendant Stout positively highlighted Avandia and its contribution to the Company's financial success, stating, in pertinent part, as follows:

So let's move now to our second largest franchise which is Avandia. If you go to the next slide, you see in total, the Avandia franchise grew 22% to £355 million in the third quarter again with strong sales acrossed all the region. And as you can see on the slide, the growth rate is very consistent. I also just wanted to point out that in the first three quarters Avandia has already achieved sales of almost £1 billion. Obviously we've had tremendous success with Avandia, but I want to continue to – to emphasize that we do not expect the growth rate to slow down over the next couple of years.

[Emphasis added.]

51. The statement referenced above in ¶50 was materially false and misleading for the reasons set forth in ¶49.

52. On February 8, 2006, Glaxo issued a press release announcing its financial results for the fourth quarter of 2005 and fiscal year 2005, the periods ending December 31, 2005. The press release was also filed with the SEC as an exhibit to a Form 6-K, which was signed by Defendant Bicknell. For the year ending 2005, the Company reported earnings of 82.6p per share, up from 68.1p per share for the year ending 2004. The press release specifically highlighted the performance of Avandia as one of the Company's "key growth products." Defendant Garnier commented on the earnings announcement and the positive contribution of Avandia, stating, in pertinent part, as follows:

Looking into 2006, the strong growth seen from key products such as Seretide/Advair, *Avandia* and from our vaccines business is set to continue. . . .

[Emphasis added.]

Dubbing Avandia as one of Glaxo's "key growth drivers", the press release added:

Avandia/Avandamet (+18% to £1.3 billion) continues to maintain its leadership position in the TZD [thiazolidinedione] class of anti-diabetic agents.

53. Also on February 8, 2006, the Company hosted a conference call with analysts and investors to discuss Glaxo's fourth quarter of 2005 financial results. During the conference call, Defendant Stout highlighted Avandia, stating, in pertinent part, as follows:

We still see Advair, Seretide, and *Avandia* as well as our vaccine portfolio as *significant growth drivers*.

[Emphasis added.]

- 54. The statements referenced above in ¶¶52 and 53 were each materially false and misleading for the reasons set forth in ¶49.
- 55. On March 3, 2006, Glaxo filed its 2005 Annual Report on Form 20-F with the SEC (the "2005 Annual Report"), which was signed by Defendant Heslop and confirmed the previously announced financial results. In the 2005 Annual Report, Defendant Garnier specifically emphasized

that the future success of the Company would be driven by products such as Avandia: "Looking into 2006, the strong growth seen from key products [including Avandia] and from our vaccines business is expected to continue. . . ." Separately, the "Outlook" section of the 2005 Annual Report's "Report of the Directors" pointed to Avandia as a key growth product for the Company. In doing so, the 2005 Annual Report stated, in pertinent part, as follows:

Sales growth of existing products and launch of new products are key drivers of GSK's business performance. *The strong growth seen from key products such as* Seretide/Advair, *Avandia*/Avandamet and from GSK's vaccines business is expected to continue in 2006.

[Emphasis added.]

- 56. The statements referenced above in ¶55 were each materially false and misleading when made for the reasons stated above in ¶49. In addition, at the time the statements were made, Defendants were aware of Glaxo's (more expansive) Second Meta-Analysis, which showed an estimate of excess risk of ischemic cardiovascular events associated with the use of Avandia that was even greater than the risk portrayed in the First Meta-Analysis. Based on this adverse information, coupled with the results from the First Meta-Analysis, Defendants lacked a reasonable basis for their positive statements about Avandia and its growth prospects.
- 57. On April 27, 2006, Glaxo issued a press release announcing its financial results for the first quarter of 2006. The press release was also filed with the SEC as an exhibit to a Form 6-K, which was signed by Defendant Bicknell. For the first quarter of 2006, the Company reported earnings of 26.5p per share, up from 21.1p per share for the first quarter of 2005. In the press release, Avandia was called one of the Company's "key growth drivers." The press release further stated:

Sales of the Avandia product group, for the treatment of type 2 diabetes, grew 19% to £414 million. Strong growth was reported in all regions with sales in the USA up 17% to £294 million; in Europe up 12% to £57 million; and in International markets up 37% to £63 million.

- 58. The statement referenced above in ¶57 was materially false and misleading for the reasons set forth in ¶56.
- 59. On July 26, 2006, Glaxo issued a press release announcing its financial results for the second quarter of 2006, the period ending June 30, 2006. The press release was also filed with the SEC as an exhibit to a Form 6-K, which was signed by Defendant Bicknell. For the second quarter, the Company reported earnings of 23.3p per share, up from 20.4p per share for the second quarter of 2005. Defendant Garnier, in "commenting on the performance in the quarter and GSK's outlook" attributed the Company's ability "to raise our earnings guidance" for 2006 to pharmaceutical sales growth, including a 32% increase in sales of Avandia.
- 60. The statement referenced above in ¶59 was materially false and misleading for the reasons set forth in ¶56.
- 61. On October 26, 2006, Glaxo issued a press release announcing its financial results for the third quarter of 2006, the period ending September 30, 2006. The press release was also filed with the SEC as an exhibit to a Form 6-K, which was signed by Defendant Bicknell. For the third quarter, the Company reported earnings of 24.7p per share, up from 21.3p per share for the third quarter of 2005. The press release specifically highlighted the contributions that Avandia was making to the Company's financial results, stating: "The Avandia family of products, for the treatment of type 2 diabetes, continues to perform well with sales up 11% to £378 million in the quarter." The press release also highlighted the DREAM study, stating, in pertinent part, as follows:

In September, results of the landmark DREAM study were presented to the European Association for the Study of Diabetes. These data demonstrated that Avandia reduced the risk of developing type 2 diabetes by 62% relative to placebo, among people at high risk of developing type 2 diabetes. This highly statistically significant reduction of 62% (p<0.0001) was additive to standard counselling on healthy eating and exercise, and is the first evidence that Avandia can reduce the risk of progression from pre-diabetes to type 2 diabetes in high-risk patients.

62. Also on October 26, 2006, the Company hosted a conference call with analysts and investors to discuss Glaxo's third quarter of 2006 financial results. During the conference call, Defendant Garnier positively described Avandia, stating, in pertinent part, as follows:

This is a big engine. This is not a product that is going to stall anytime soon, and we are prepared to back it up in a way that's going to be a big driver for the Company for years to come.

Defendant Stout highlighted the DREAM trial, stating, in pertinent part, as follows:

In September, the results of the DREAM trial were presented at the European Association for the Study of Diabetes conference. This was a huge study, over three years and over 5,000 patients. The results showed that, as we had expected, Avandia does significantly reduce the risk of patients progressing into type 2 diabetes. Most of the key opinion leaders were extremely excited about these results, and they feel they are very supportive of Avandia and the treatment guidelines being changed.

- 63. The statements referenced above in ¶¶61 and 62 were materially false and misleading for the reasons set forth in ¶56. In addition, Defendant Stout's specific reference to the purported positive results from the DREAM study further created an obligation to disclose the adverse information from the First Meta-Analysis and Second Meta-Analysis.
- 64. On February 8, 2007, Glaxo issued a press release announcing its financial results for the fourth quarter of 2006 and fiscal year 2006, the periods ending December 31, 2006. The press release was also filed with the SEC as an exhibit to a Form 6-K, which was signed by Defendant Bicknell. For the year ending 2006, the Company reported earnings of 95.5p per share, up from 82.6p per share for the year ending 2005. The press release highlighted the financial contribution made by sales of Avandia, stating, in pertinent part, as follows:

Sales of Avandia products, for the treatment of type 2 diabetes, grew 24% to £1.2 billion in the USA. In Europe, sales grew 40% to £217 million driven by the increasing use of Avandamet. Sales in International markets rose 19% to £234 million.

The press release also positively described the ADOPT study as indicative of the positive attributes of Avandia, stating, in pertinent part, as follows:

In December, GSK presented data from the landmark ADOPT study, which demonstrated that Avandia is more effective than metformin, or sulphonylurea, in long-term blood sugar control in type 2 diabetes. These data are in addition to those recently presented from the DREAM study, which showed that Avandia can reduce the risk of progression to type 2 diabetes. Data from both these studies are expected to be filed with regulatory agencies during the first half of 2007.

65. Also on February 8, 2007, the Company hosted a conference call with analysts and investors to discuss Glaxo's financial results for the fourth quarter and fiscal year 2006. During the conference call, Defendant Stout positively described the DREAM and ADOPT studies, stating, in pertinent part, as follows:

Of course, the really important news for 2006 was the release of two very important outcomes trials, DREAM, and more importantly, the ADOPT study, which you all heard about in December. Just to remind you what the results of that trial were, were I think we exceeded everyone's expectations, in some cases even our own, where we beat metformin on performance and we tied them on the cardiovascular safety. So this is a very positive study.

- 66. The statements referenced above in ¶¶64 and 65 were materially false and misleading for the reasons set forth in ¶56 and 63.
- 67. On March 2, 2007, Glaxo filed its 2006 Annual Report on Form 20-F with the SEC (the "2006 Annual Report"), which was signed by Defendant Heslop and confirmed the previously – announced financial results. In the 2006 Annual Report, Defendant Garnier highlighted the current and future successes of the Company's key pharmaceutical products, including Avandia, stating, in pertinent part, as follows:

Your company delivered a strong financial performance in 2006. Turnover of £23.2 billion is an increase of 9 per cent at constant exchange rates (CER)*. Earnings per share (EPS) were 95.5 pence, with growth of 19 percent. This performance was driven by sales of key pharmaceutical products including. . . the Avandia group of products for diabetes. . . .

Looking ahead, we expect new clinical data to help deliver growth from Seretide/Advair and the Avandia group of products, and continued good performance from our vaccines business.

The 2006 Annual Report also positively described the DREAM and ADOPT studies, stating, in pertinent part, as follows:

In December, GSK presented data from the landmark ADOPT study, which demonstrated that Avandia is more effective than metformin, or a sulphonylurea, in long-term blood sugar control in type 2 diabetes. These data are in addition to those recently presented from the DREAM study, which showed that Avandia can reduce the risk of progression to type 2 diabetes. Data from both these studies are expected to be filed with regulatory agencies during the first half of 2007.

The "Outlook" section of the 2006 Annual Report added: "Sales growth of existing products and launch of new products are key drivers of GSK's business performance. **The strong growth seen** from key products such as... Avandia... is expected to continue in 2007." [Emphasis added.]

68. The statements referenced above in ¶67 were each materially false and misleading for the reasons set forth in ¶56 and 63 above.

The Truth Is Revealed

- 69. On May 21, 2007, *The New England Journal of Medicine* published a meta-analysis conducted by Dr. Stephen Nissen entitled "Effect of Rosiglitazone on the Risk of Myocardial Infarction and Death from Cardiovascular Causes," which concluded that Avandia poses a statistically significant risk of cardiac side-effects. Specifically, the article states that "[R]osiglitazone [Avandia] was associated with a [statistically] significant increase in the risk of myocardial infarction."
- 70. Later that same day, the FDA issued a safety alert, which recognized the increased risk of heart attack through the use of Avandia. The FDA's alert specifically addressed the potential risks identified by its own pooled analysis of completed controlled clinical trials, which demonstrated a potentially significant increase in the risk of heart attack and heart-related deaths in patients taking Avandia. According to the FDA's initial analysis of Glaxo's meta-

analyses, the data expressed a significant concern with respect to the excess risk of heart attacks in Avandia-treated patients.

- 71. As a result of the FDA's alert and Dr. Nissen's findings, on May 21, 2007, the price of Glaxo ADSs dropped \$4.53 per ADS, or 7.8%, on unusually high trading volume. In reaction to the same news, Glaxo's ordinary shares on the LSE dropped 74 pence. The Company's ADSs and ordinary shares continued to lose value as the impact of the negative publicity was digested by investors, eventually falling from \$57.71 per share and 1464 pence per share to \$53.18 per share and 1390 pence per share, respectively on May 29, 2007.
- 72. On May 31, 2007, an article in *The Wall Street Journal* reported that in a letter published on the website of *The Lancet*, a medical journal, Glaxo's chief medical officer, Ronald Krall, wrote that the Company had found indications of increased risk of heart attacks associated with Avandia in its own previously conducted meta-analyses of clinical studies of Avandia.
- Avandia, Defendant Garnier admitted that Glaxo had performed its own meta-analyses and also found that Avandia caused an increased risk of heart attack. Defendant Garnier also acknowledged in the article that Glaxo had failed to adequately communicate the risks of Avandia. The following question and answer is illustrative: Dr. Garnier was asked, "Has Glaxo done everything it could to study Avandia and communicate its risks to the public?" In response, Dr. Garnier stated: "We're not perfect. I'm sure. With 20-20 hindsight we could have done more."
- 74. On July 30, 2007, the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety Management Advisory Committee held a hearing regarding Avandia. At that hearing, Joy D. Mele, M.S., a statistician at the FDA CDER Office of Biostatistics, stated, "we find the increased risk of myocardial ischemia associated with rosiglitazone [Avandia] compared to

placebo as nominally statistically significant. . . . "Karen Mahoney, M.D., an FDA medical officer, further stated that "[t]he FDA meta-analysis was consistent with a significantly increased risk of total myocardial ischemic events for rosiglitazone [Avandia] versus comparator." David Graham, M.D., M.P.H., Associate Director for Science and Medicine at the FDA, stated "when we get to the question does rosiglitazone [Avandia] increase cardiovascular risk, we believe that the answer to that question is yes. The FDA meta-analysis has shown an increase of between 20 and 70 percent in ischemic heart disease risk within 6 to 12 months of rosiglitazone [Avandia] use compared to its non-use. . . . In DREAM we saw a risk increase of about 40 percent." Curt. D. Furberg., M.D., Ph.D., a temporary member of the Endocrinologic and Metabolic Drugs Advisory Committee, stated "[t]he placebo-controlled trials answer the questions does rosiglitazone [Avandia] increase the risk of cardiovascular events. I think the answer is clear. There is an excess risk, statistically significant." The FDA advisory committee, in a 20-3 vote, agreed that Avandia was tied to increased ischemic risk, meaning an increased risk for heart attacks.

75. When analysts became aware of Dr. Nissen's findings and the corresponding risk of heart attack associated with Avandia, analysts downgraded Glaxo. The downgrades were attributed to the sales losses and negative earnings impact that Avandia's risk of heart attacks would have on Glaxo's overall company performance. On June 7, 2007, for example, Bear Stearns trimmed its earnings per share estimates for Glaxo, stating: "In view of the risks to GSK's US Avandia franchise, we have reduced our Avandia forecasts." The report added that "Avandia's cardiovascular risk profile remains an overhang on the stock. . . ." Then, on July 25, 2007, Bear Stearns downgraded Glaxo and wrote: "Since May 23, 2007, when Dr. Nissen's meta-analysis on Avandia's CV risk profile was published in the *NEJM*, GSK shares have come off 5.4% *to reflect*

the expected earnings impact. We cut our Avandia sales projections on June 8, 2007. . . . "
[Emphasis added.]

- 76. On October 24, 2007, Glaxo announced that it would be implementing layoffs and cost cuts after a 38% drop in sales of Avandia significantly hurt the Company's third quarter earnings.
- 77. On November 14, 2007, the FDA issued a press release announcing that Glaxo had agreed to add new information to the existing boxed warning in Avandia's labeling about potential increased risk for heart attacks.
- 78. In November 2007, the Finance Committee issued a report entitled "The Intimidation of Dr. John Buse and the Diabetes Drug Avandia." In the report, the Finance Committee described the findings of its investigation in detail. The Finance Committee found that, in 1999, Buse had expressed concerns regarding the cardiovascular risks including heart attacks associated with Avandia. Glaxo was not only knowledgeable about the significant link between Avandia and heart attacks, but, according to the Finance Committee's report, Defendants Garnier and Stout, as well as then research chief for the Company, Tachi Yamada, were participants in a concerted effort to intimidate Buse and silence his efforts to publicize Avandia's potential negative cardiovascular effects. The Finance Committee's report stated that Glaxo stifled Buse by complaining to his superiors at the University of North Carolina, calling him a "renegade" and ultimately threatening him with the prospect of facing a lawsuit.
- 79. On February 7, 2008, Glaxo issued a press release announcing its financial results for the fourth quarter of 2007 and fiscal year 2007, the period ending December 31, 2007. Among other things, the Company reported that "the decline in Avandia sales, together with increased generic

competition in the USA, will adversely impact our earnings in 2008. . . . " The Company further reported that sales of Avandia fell 29% "following publication in May of a meta-analysis."

- 80. On March 25, 2008, the FDA issued its Warning Letter to Glaxo, which stated, among other things, that Glaxo had "failed to report data relating to clinical experience, along with other data and information, for Avandia, as required" by applicable regulations. In addition, the FDA Warning Letter indicated that Glaxo had failed to report nine Avandia-related studies to the FDA and that those studies were not disclosed the FDA until Glaxo made an amendment to its 2007 NDA Annual Report in September 2007. The FDA Warning Letter also criticized Glaxo for failing to properly report the 49653/211 and RECORD studies to the FDA, which were studies triggered by adverse drug experiences and were directed to cardiovascular issues. The FDA noted that Glaxo's failure to properly report these studies to the FDA was not conducive to the "agency's ability to spot drug safety trends."
- 81. On April 23, 2008, Glaxo announced its financial results for the first quarter of 2008 and reported that Avandia sales had declined 56%, with sales in the U.S. down 66%, sales in Europe down 14% and sales in international markets down 44%.

Additional Scienter Allegations

82. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly or recklessly substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Glaxo, their control over, and/or receipt and/or modification of Glaxo's allegedly materially misleading misstatements and/or

their associations with the Company which made them privy to confidential proprietary information concerning Glaxo, participated in the fraudulent scheme alleged herein.

- 83. Defendants knew or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public. The ongoing fraudulent scheme described in this complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of the personnel at the highest level of the Company, including the Individual Defendants.
- Defendants were motivated to conceal the truth about the First and Second Meta-84. Analyses in order to protect and maintain sales of Avandia. As the truth about Avandia has become known, sales have plummeted.
- 85. During the Class Period, while the Company's stock and ADSs were artificially inflated due to Defendants' false and misleading statements, the following Individual Defendants, while in possession of undisclosed adverse information, sold more than 250,000 shares of their personally-held Glaxo ADSs for proceeds of approximately \$27.5 million. The following chart sets forth the Class Period insider trading, which was unusual and suspicious; both in timing and in amount:

Name	Date	Shares	Price	Proceeds
Garnier, Dr. Jean-				
Pierre	10/30/2006	45,500	\$53.21	\$2,421,055
	2/8/2007	51,100	\$55.81	\$2,851,891
	2/13/2007	17,411	\$57.37	\$998,869
		114,011		\$6,271,815

Name	Date	Shares	Price	Proceeds
Greig, R ⁴	5/12/2006 2/23/2007	600	\$57.15	\$34,290
C ,		45,000	\$56.82	\$2,556,900
		45,600		\$2,591,190
Louv, W ⁵	2/27/2007	325	\$56.46	\$18,350
		325		\$18,350
Phelan, Daniel ⁶	7/31/2006	23,517	\$55.28	\$1,300,000
	2/8/2007	149,623	\$55.81	\$8,350,459
	2/21/2007	19,721	\$57.78	\$1,139,479
		192,861		\$10,789,938
Stout, David M.	2/8/2007	3,475	\$55.87	\$194,148
,		3,475		\$194,148
Yamada, Tadataka ⁷	12/6/2005	74,866	\$50.50	\$3,780,733
,	5/3/2006	21,380	\$56.77	\$1,213,742
		96,246		\$4,994,475
Ziegler, John B. ⁸	10/28/2005	21,596	\$52.50	\$1,133,790
	12/19/2005	29,417	\$52.25	\$1,537,038
		51,013	+02.20	\$2,670,828
	Total:	503,531		\$27,530,744
			=	=======================================

Russell Greig was, at all relevant times, the Company's President, Pharmaceuticals International.

William Louv has been Glaxo's Senior Vice President, Information Technology and Chief Information Officer since January 2007. Prior to that appointment, Louv was Senior Vice President, Information Technology for the Company's U.S. Pharmaceuticals business.

Daniel Phelan was, at all relevant times, the Company's Senior Vice President, Human Resources.

Tadataka "Tachi" Yamada was the Company's Chairman, Research and Development from December 2000 until June 2006. He is currently President, Global Health Program at the Bill & Melinda Gates Foundation.

John B. Ziegler was Glaxo's President, Consumer Healthcare until his planned retirement on January 31, 2006.

Loss Causation/Economic Loss

- 86. During the Class Period, Defendants failed to disclose material adverse information concerning Avandia and safety issues attendant to its use. When Defendants' prior misrepresentations and fraudulent conduct were later disclosed and became apparent to the market, the price of Glaxo ADSs and ordinary shares fell precipitously as the prior artificial inflation came out of Glaxo's ADS and ordinary share price. As a result of their purchases of Glaxo ADSs and/or ordinary shares during the Class Period, Plaintiffs and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.
- 87. Defendants' misrepresentations caused and maintained the artificial inflation in Glaxo's ADS and ordinary share price throughout the Class Period and until the truth was revealed to the market.
- 88. Defendants' false and misleading statements had their intended effect and caused Glaxo's ADSs and ordinary shares to trade at artificially inflated levels, reaching as high as \$59.98 per share and 1581 pence, respectively, during the Class Period.
- 89. As a direct result of truth revealed to the market on May 21, 2007, Glaxo's ADS price dropped 7.8% that day on unusually high volume, falling from \$57.71 per share to \$53.18 per share. Glaxo's ordinary shares on the LSE dropped from 1464 pence to 1390 pence. The Company's ADSs and ordinary shares continued to lose value as the impact of the negative information was digested by investors, eventually falling to \$52.06 per share and 1306 pence per share, respectively, on May 29, 2007. This decline removed the inflation from Glaxo's ADS and ordinary share price, causing real economic loss to investors who had purchased the ADSs and ordinary shares during the Class Period.

- 90. In sum, as the truth about Defendants' fraud was revealed, the Company's ADS and ordinary share price plummeted, the artificial inflation came out of the ADSs and ordinary shares and Plaintiffs and other members of the Class were damaged, suffering substantial economic losses.
- 91. The decline in Glaxo's ADS and ordinary share price at the end of the Class Period was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of Glaxo's ADS and ordinary share price declines negate any inference that the loss suffered by Plaintiffs and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Plaintiffs and other members of the Class was a direct result of Defendants' fraudulent scheme to artificially inflate Glaxo's ADS and ordinary share price and the subsequent significant decline in the value of Glaxo's ADSs and ordinary shares when Defendants' prior misrepresentations and other fraudulent conduct was revealed.
- 92. The price of Glaxo's ADSs and ordinary shares sharply declined immediately in response to the disclosure of the increased risk of heart attack associated with Avandia.
- 93. Analysts likewise downgraded Glaxo upon learning of Avandia's association with increased risk of heart attack. Such downgrades were directly attributed to the anticipated loss of Avandia sales and the overall negative earnings impact that knowledge of Avandia's risk of heart attacks would have on Glaxo's growth or performance. For example, on June 8, 2007, Bear Stearns cut their Avandia sales projections in response to the news that the drug presented an increased risk of heart attacks. Then, on July 25, 2007, Bear Stearns downgraded Glaxo again for the same reasons.

No Safe Harbor

94. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Glaxo who knew that those statements were false when made.

COUNT I

For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

- 95. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.
- 96. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
 - 97. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:
 - (a) Employed devices, schemes, and artifices to defraud;

- (b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- (c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiffs and others similarly situated in connection with their purchases of Glaxo ADSs and ordinary shares during the Class Period.
- 98. Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Glaxo ADSs and ordinary shares. Plaintiffs and the Class would not have purchased Glaxo ADSs and ordinary shares at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.
- 99. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of Glaxo ADSs and ordinary shares during the Class Period.

COUNT II

For Violation of Section 20(a) of the Exchange Act Against All Defendants

- 100. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.
- 101. The Individual Defendants acted as controlling persons of Glaxo within the meaning of Section 20 of the Exchange Act. By virtue of their positions and their power to control public statements about Glaxo, the Individual Defendants had the power and ability to control the actions of Glaxo and its employees. Glaxo controlled the Individual Defendants and its other officers and

employees. By reason of such conduct, Defendants are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the Class, pray for judgment as follows:

- A. Declaring this action to be a class action properly maintained pursuant to Rule 23 of the Federal Rules of Civil Procedure;
- B. Awarding Plaintiffs and other members of the Class damages together with interest thereon;
- C. Awarding Plaintiffs and other members of the Class costs and expenses of this litigation, including reasonable attorneys' fees, accountants' fees and experts' fees and other costs and disbursements; and
- D. Awarding Plaintiffs and other members of the Class such equitable/injunctive or other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

DATED:, 2008	COUGHLIN STOIA GELLER
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